

REMARKS

Applicant thanks the Examiner for the very thorough consideration given the present application. Claims 1-2, 5-6 and 8 are currently pending in this application. Claim 1 has been withdrawn from further consideration. Claim 7 has been cancelled. No new matter has been added by way of the present amendment. For instance, the amendment to claim 1, as well as new claim 8, are supported by the Specification at, for example, pages 1, 7 and 11, and the Figures. Accordingly, no new matter has been added.

In view of the amendments and remarks herein, Applicant respectfully requests that the Examiner withdraw all outstanding rejections and allow the currently pending claims.

Issues Under 35 U.S.C. § 103(a)

Claims 2 and 5-7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Yoshida (U.S. 2003/0232450) (hereinafter Yoshida '450) in view of Takanori et al. (JP 2002-086399) (hereinafter Takanori '399). Applicant respectfully traverses.

The Examiner asserts that Yoshida '450 discloses a method for manufacturing a microfluidic device comprising the steps of: forming a resin layer 2 on a substrate 1, forming a groove or channel 5 by removing a portion of the resin layer by laser processing and forming a "throughhole" or inlet via laser processing. The Examiner acknowledges that Yoshida '450 does not teach or suggest the formation of subsequent resin layers to form a three-dimensional fluidic circuit and relies on the teachings of Takanori '399 to overcome this deficiency.

Applicant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, the prior art reference (or

references when combined) must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Additionally, there must be a reason why one of ordinary skill in the art would modify the reference or combine reference teachings to obtain the invention. A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int'l Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). There must be a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *Id.* The Supreme Court of the United States has recently held that the "teaching, suggestion, motivation test" is a valid test for obviousness, albeit one which cannot be too rigidly applied. *Id.* Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *Id.*

The present invention is directed, *inter alia*, to a three-dimensional flow path which is composed of grooves and throughholes and which can mix fluids in a microspace or passage. Neither Yoshida '450 nor Takanori '399 disclose a fluid path that can mix plural fluids. Moreover, none of the cited references discloses or suggests the presently claimed processing steps which form the specific three-dimensional fluid path of the present invention.

As previously discussed, in recent years, development of a micro total analysis system (μ -TAS) has advanced, including applications of μ -TAS to genetic diagnosis, poison inspection, and the like. However, up until the present time, μ -TAS has not been successfully reduced to practice. For instance, if the devices are manufactured by means of impractical steps such as

photolithography (see Takanori '399), which lacks design freedom, the manufacturing time and costs are so excessive so as to be unsuitable for practical use in applicable fields.

In view of the above, alternatives have been proposed, including a fluidic device, a part of which can be recycled (see Yoshida '450). However, this device has a two-dimensional (planar) fluid flow path. When a plurality of fluids are joined, respective fluids flow in parallel, and sufficient mixing of the fluids is not accomplished. Therefore, mixing must be forced by providing an electrode in the fluidic device, which reduces the cost-effectiveness of the device. In addition, in order to perform the above-described electrical mixing, the fluid is limited to fluids in which electric migration occurs, and thus, the scope in which the device can be applied is remarkably limited (see page 3, line 14 to page 4, line 3 of the present specification).

The present invention aims to solve the above-described problems. Specifically, the present invention exhibits the following advantages over the procedures of the prior art, such as those disclosed by Yoshida '450 and Takanori '399:

- (i) The present method significantly reduces the number of steps required.
- (ii) The present method can form a three-dimensional flow path (i.e. processing in thickness-direction) with much improved accuracy because a flow path is created by laminating a film and laser-ablating the film. In contrast, it is very hard to stack thin films accurately when using photolithography.
- (iii) The present method can form a three-dimensional fluid path according to a dry process that directly utilizes the layers. Takanori '399 prepares a fluid path by means of a wet process (photolithography). The present invention can prepare a three-dimensional fluid path that is more complex, due to the specific manufacturing method developed by Applicant.

(iv) The present method allows for the preparation of a three-dimensional path by using a thick film. In contrast, it is very hard to process a thick film in photolithography.

(v) In the present invention, the substrate can be re-used.

Clearly, the present inventor has reduced to practice a method applicable to new genetic diagnosis and biochemical analysis procedures, in a wide range of technology areas and medical fields, which is not obvious over the prior art.

As discussed in the Response to Office Action filed on May 12, 2008, some of the technical features of the present invention include: (a) the lamination of resin film layers; (b) formation of micro-fine fluid flow path by laser processing; and (c) lack of unnecessary materials and processing steps.

The present invention employs a step of stacking on a substrate resin films formed by a lamination method (see page 9, line 8 to page 10, line 1 of the present specification). This step is different from the step of processing using a coated film of a fluid resin (Takanori '399) and provides a film layer on a substrate which does not flow out of the resin because of its stable form. Thereby, handling and processing are largely improved by the method of the present invention.

Moreover, the present invention employs a step of forming a fluid flow path by laser ablation (see page 8, line 17 to page 9, line 7 of the present specification; see also claim 2 and dependent claims thereof). Therefore, by arbitrarily moving a laser irradiating position, a fluid flow path can be formed in a desired shape without substantial limitation. For example, even complicated micro-fine three-dimensional fluid flow paths, as shown in Figures 1 and 2 of the present specification, can be manufactured by forming a groove and a throughhole while each

layer is precisely controlled. Accordingly, even when the structure of a fluid flow path is frequently changed in order to provide customized medical treatment to individual patients, the device of the present invention can effectively meet particular needs without cost increases.

Additionally, in the present invention, all fluid flow paths from an inlet to an outlet, as shown in Figures 1 and 2, are formed in laminated resin films (see claim 2). Accordingly, the above-described laser processing method is used to form micro-fine fluid flow paths in all film layers. The device of the present invention does not require unnecessary steps and materials such as a pipe and a temporary substrate (Takanori '399), and high manufacturing efficiency and cost-effectiveness are achieved.

Yoshida '450 discloses the formation of a planar flow path, rather than a three-dimensional flow path, as presently claimed. In Yoshida '450, the layer on which the grooves are formed is only a single layer. Therefore, Yoshida '450 neither describes nor suggests the formation of a three-dimensional flow path by forming grooves on a plurality of layers. Takanori '399 fails to cure these deficiencies.

Takanori '399 discloses a method of manufacturing a microdevice comprising: 1) a step of coating a fluid resin on a temporary substrate to form a coated film, 2) a step of fitting a photomask to the coated film, 3) a step of photo-curing a part of the coated film by irradiating the part with an ultraviolet ray through the photomask, and 4) a step of washing out an uncured part of the coated film.

As previously discussed, lithography is essential in Takanori '399, in order to form cut portions in a semi-cured coating film. Lithography is essentially a wet process. This should be apparent, for example, from the description at paragraph [0004] of Takanori '399 (which

corresponds to the description in column 1, lines 35-46 of U.S. 7,220,334 (Takanori's counterpart U.S. application)). The method of Takanori '399 forms a resin cut portion by "patterning exposure and development" (Takanori '399, paragraph [0004]). In the patterning operation, "except for the portion which should serve as a cut portion, the uncured composition (x) is irradiated with an active energy ray, thereby semi-curing the composition (x) at the irradiated portion and leaving the non-irradiated portion as a cured portion" (Takanori '399, paragraph [0086]; U.S. 7,220,334, column 13, lines 36-46). In the development operation, the uncured composition is removed to form a resin cut portion (Takanori '399, paragraph [0097]; U.S. 7,220,334, column 15, lines 11-15). Evidently, these "patterning exposure and development" operations correspond to lithography.

In stark contrast, the present invention requires laser processing. Therefore, the present invention has no relationship to photolithography.

Moreover, Takanori '399 requires a step of transferring a coated film with a temporary substrate. In Takanori '399, in order to keep and fix the shape of the deleted portion 3 of the coated film 2 formed on the temporary substrate 1, the coated film is transferred to the resin layer 5 on the main substrate 4 prepared separately (see Figure 3 of Takanori '399). Thereafter, the temporary substrate 1 is removed. Then, a substrate 6 having a resin layer 7 formed thereon is prepared separately from the main substrate 4, and the substrate 6 is bonded onto the transferred coated film 2' so that the resin layer 7 faces the transferred coated film 2' (see paragraphs [0188] to [0192] of Takanori '399). In contrast, the present substrate is re-usable, thus further decreasing costs.

In the method of Takanori '399, it is necessary to accurately transfer the coated film on the temporary substrate to the resin layer of the main substrate. In particular, in order to form a three-dimensional flow path, it is necessary to transfer accurately the deleted portion on the upper layer superposed onto the deleted portion of the lower layer. This process has a high level of difficulty, and the lack of accuracy can cause a misalignment in the circuit. In stark contrast, the present invention requires no transfer processing using temporary substrates.

Clearly, the cited references, alone or in combination, fail to teach or suggest every limitation of the instant invention. For this reason alone, this rejection should be withdrawn.

Furthermore, assuming *arguendo* that Takanori '399 cured the deficiencies of Yoshida '450, it is noted that references cannot be arbitrarily combined. There must be a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *KSR Int'l Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). Moreover, according to MPEP 2143.01, the combination of references cannot change the principle of operation of the primary reference or render the reference inoperable for its intended purpose.

Takanori '399 utilizes photolithography as an essential technology. Thus, it would be impossible to also apply the lamination method of Yoshida '450, when manufacturing a microfluidic device. Therefore, a *prima facie* case of obviousness has not been established.

Accordingly, reconsideration and withdrawal of the present rejection are respectfully requested.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Marc S. Weiner, Reg. No. 32,181 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.147; particularly, extension of time fees.

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Respectfully submitted,

By 

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